K010008

JUL 1 6 2001

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010008.

SUBMITTER:	Micronet Medical, Inc. 1839 Buerkle Road White Bear Lake, MN 55110 Phone: 651-773-3181 Fax: 651-773-3190
CONTACT PERSON: **TITLE:**	Charles Lehman Vice President, Operations and Quality
DATE PREPARED:	July 11, 2001
TRADE NAME:	Axxess™ Spinal Cord Stimulation Lead
COMMON NAME:	Implanted Spinal Cord Stimulation Lead
CLASSIFICATION:	21 CFR 882.5880, Implanted Spinal Cord Stimulator for Pain Relief Class II
PRODUCT CODE:	GZB
PREDICATE DEVICE(S):	Medtronic Specify® Lead Model 3998, Medtronic Pisces-Quad® Lead Model 3487, Medtronic Pisces-Quad® Compact Model 3887 and ANS Quattrode® Lead Model 2193.
DEVICE DESCRIPTION:	Micronet Medical, Inc.'s Axxess™ Spinal Cord Stimulation Leads, Model 8000 Series, are implantable devices consisting of four spaced electrodes connected by wires within a cover sheath. The leads are introduced into the epidural space and connected to a pulse generator via an extension wire. The Axxess Lead package includes one lead, and implant accessories consisting of one epidural needle, two stylets, a screening cable and two lead anchoring sleeves. The implant accessories may be sold separately for replacement purposes.
INDICATIONS FOR USE:	The Axxess™ Spinal Cord Stimulation Lead is designed to be utilized as the lead component of spinal cord stimulation systems and is used to aid in the management of chronic pain of the trunk and/or extremities. The Axxess Lead system is designed to be used with the following devices:

- The Medtronic® Mattrix® Model 3272 RF system receiver and compatible transmitter or
- The Medtronic® X-trel® Model 3470 RF system receiver and compatible transmitter using the Model 7495 Quadripolar extension, and
- The Medtronic® Model 3550-05 Percutaneous Extension with the Medtronic® Model 3550-03 Screener Cable, and
- The Medtronic® DualScreen™ Screener Model 3628

FUNCTIONAL & SAFETY TESTING:

The Micronet Medical, Inc. Axxess™ Spinal Cord Stimulation Lead was examined and tested for functionality and performance. Complete testing included electrical performance testing, mechanical performance testing, and label and packaging testing. This testing demonstrated that the Axxess Lead met all required specifications.

CONCLUSION:

The Axxess Spinal Cord Stimulation Lead, Model 8000 Series, is substantially equivalent to Medtronic Leads, Model 3998 (Specify®), Model 3487 (Pisces-Quad®) and Model 3887 (Pisces-Quad® Compact) and the ANS Quattrode® Model 2193 Lead in intended use, design and functional performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2001

Mr. Charles Lehman
Vice President, Operations and Quality
Micronet Medical, Inc.
1830 Buerkle Road
White Bear Lake, Minnesota 55110

Re: K010008
Trade/Device Name: Axxess™ Spinal Cord Stimulation Lead, Model 8000 Series
Regulation Number: 882.5880
Regulatory Class: II
Product Code: GZB
Dated: May 1, 2001
Received: May 2, 2001

Dear Mr. Lehman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Page

510(k) Number (if known): K010008

Device Name:
Axxess™ Spinal Cord Stimulation Lead, Model 8000 Series

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010008